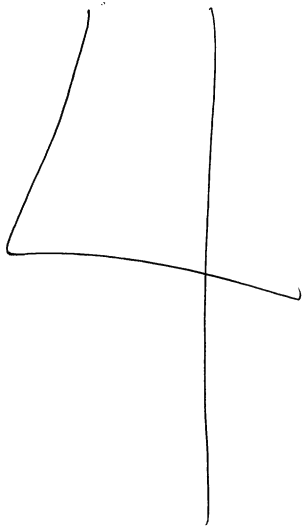

PATENT
Docket No. 01723326

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application of:	Jeffrey Owen Phillips	
Serial No.:	09/481,207	Examiner: Fan, J.
Filed:	January 11, 2000	Group Art Unit: 1625
For:	Novel Substituted Benzimidazole Dosage Forms and Method of Using Same	

AMENDMENT AND RESPONSE

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

In response to the Office Action dated March 23, 2001, please amend the above-captioned patent application as follows:

IN THE CLAIMS:

Claims 1, 4-7, and 9-15 are pending in this application. Claims 2-3, 8, and 16-22 were previously withdrawn from consideration. Applicant hereby cancels all pending claims in favor of the below new claims without prejudice and reserves the right to claim the subject matter of the cancelled and withdrawn claims in this or any related application.

23. (New) A solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) a proton pump inhibitor (PPI) selected from a group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole and leminoprazole; and

(b) at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the PPI by gastric acid so as to achieve bioavailability of the PPI in a subject after oral administration of the dosage form.

24. (New) The dosage form as recited in Claim 23 wherein the bioavailability of the PPI is sufficient to elicit a therapeutic effect.

25. (New) The dosage form as recited in Claim 23 wherein the PPI is present in a therapeutically effective amount.

26. (New) The dosage form as recited in Claim 23 wherein the PPI comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

27. (New) The dosage form as recited in Claim 23 wherein the PPI is omeprazole.

28. (New) The dosage form as recited in Claim 23 wherein the PPI is lansoprazole.

29. (New) The dosage form as recited in Claim 23 wherein the PPI is rabeprazole.

30. (New) The dosage form as recited in Claim 23 wherein the PPI is esomeprazole.

31. (New) The dosage form as recited in Claim 23 wherein the PPI is pantoprazole.

32. (New) The dosage form as recited in Claim 23 wherein the PPI is pariprazole.

33. (New) The dosage form as recited in Claim 23 wherein the PPI is leminoprazole.

34. (New) The dosage form as recited in Claim 23 further comprising at least one flavoring agent.

35. (New) The dosage form as recited in Claim 23 further comprising an anti-foaming agent.

36. (New) The dosage form as recited in Claim 23 wherein the dosage form is a tablet.

37. (New) The dosage form as recited in Claim 23 wherein the dosage form is a powder.

38. (New) The dosage form as recited in Claim 23 wherein the dosage form is a suspension tablet.

39. (New) The dosage form as recited in Claim 23 wherein the dosage form is a chewable tablet.

40. (New) The dosage form as recited in Claim 39 further comprising aspartame.

41. (New) The dosage form as recited in Claim 23 wherein the dosage form is a capsule.

42. (New) The dosage form as recited in Claim 23 wherein the dosage form is an effervescent powder.

43. (New) The dosage form as recited in Claim 23 wherein the dosage form is an effervescent tablet.

44. (New) The dosage form as recited in Claim 23 wherein the dosage form is a plurality of pellets.

45. (New) The dosage form as recited in Claim 23 wherein the dosage form is a plurality of granules.

46. (New) The dosage form as recited in Claim 23 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

47. (New) The dosage form as recited in Claim 23 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

48. (New) The dosage form as recited in Claim 23 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

49. (New) The dosage form as recited in Claim 23 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

50. (New) The dosage form as recited in Claim 23 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate, and other magnesium salts.

51. (New) The dosage form as recited in Claim 23 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium

hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

52. (New) The dosage form as recited in Claim 23 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

53. (New) The dosage form as recited in Claim 23 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

54. (New) The dosage form as recited in Claim 23 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

55. (New) The dosage form as recited in Claim 23 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

56. (New) The dosage form as recited in Claim 23 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

57. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 36 with an aqueous medium.

58. (New) The liquid pharmaceutical composition of Claim 57 wherein the aqueous medium comprises sodium bicarbonate solution.

59. (New) The liquid pharmaceutical composition of Claim 57 wherein the aqueous medium comprises gastric secretions.

60. (New) The liquid pharmaceutical composition of Claim 57 wherein the aqueous medium comprises water.

61. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 37 with an aqueous medium.

62. (New) The liquid pharmaceutical composition of Claim 61 wherein the aqueous medium comprises sodium bicarbonate solution.

63. (New) The liquid pharmaceutical composition of Claim 61 wherein the aqueous medium comprises gastric secretions.

64. (New) The liquid pharmaceutical composition of Claim 61 wherein the aqueous medium comprises water.

65. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 38 with an aqueous medium.

66. (New) The liquid pharmaceutical composition of Claim 65 wherein the aqueous medium comprises sodium bicarbonate solution.

67. (New) The liquid pharmaceutical composition of Claim 65 wherein the aqueous medium comprises gastric secretions.

68. (New) The liquid pharmaceutical composition of Claim 65 wherein the aqueous medium comprises water.

69. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 39 with an aqueous medium.

70. (New) The liquid pharmaceutical composition of Claim 69 wherein the aqueous medium comprises sodium bicarbonate solution.

71. (New) The liquid pharmaceutical composition of Claim 69 wherein the aqueous medium comprises gastric secretions.

72. (New) The liquid pharmaceutical composition of Claim 69 wherein the aqueous medium comprises water.

73. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 40 with an aqueous medium.

74. (New) The liquid pharmaceutical composition of Claim 73 wherein the aqueous medium comprises sodium bicarbonate solution.

75. (New) The liquid pharmaceutical composition of Claim 73 wherein the aqueous medium comprises gastric secretions.

76. (New) The liquid pharmaceutical composition of Claim 73 wherein the aqueous medium comprises water.

77. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 41 with an aqueous medium.

78. (New) The liquid pharmaceutical composition of Claim 77 wherein the aqueous medium comprises sodium bicarbonate solution.

79. (New) The liquid pharmaceutical composition of Claim 77 wherein the aqueous medium comprises gastric secretions.

80. (New) The liquid pharmaceutical composition of Claim 77 wherein the aqueous medium comprises water.

81. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 42 with an aqueous medium.

82. (New) The liquid pharmaceutical composition of Claim 81 wherein the aqueous medium comprises sodium bicarbonate solution.

83. (New) The liquid pharmaceutical composition of Claim 81 wherein the aqueous medium comprises water.

84. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 43 with an aqueous medium.

85. (New) The liquid pharmaceutical composition of Claim 84 wherein the aqueous medium comprises sodium bicarbonate solution.

86. (New) The liquid pharmaceutical composition of Claim 84 wherein the aqueous medium comprises water.

87. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 44 with an aqueous medium.

88. (New) The liquid pharmaceutical composition of Claim 87 wherein the aqueous medium comprises sodium bicarbonate solution.

89. (New) The liquid pharmaceutical composition of Claim 87 wherein the aqueous medium comprises gastric secretions.

90. (New) The liquid pharmaceutical composition of Claim 87 wherein the aqueous medium comprises water.

91. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 45 with an aqueous medium.

92. (New) The liquid pharmaceutical composition of Claim 91 wherein the aqueous medium comprises sodium bicarbonate solution.

93. (New) The liquid pharmaceutical composition of Claim 91 wherein the aqueous medium comprises gastric secretions.

94. (New) The liquid pharmaceutical composition of Claim 91 wherein the aqueous medium comprises water.

95. (New) A method of treating an acid-related gastrointestinal condition, comprising orally administering to a subject a solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) a proton pump inhibitor (PPI) selected from a group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole and leminoprazole; and

(b) at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the PPI by gastric acid so as to achieve bioavailability of the PPI in the subject after oral administration of the dosage form.

96. (New) The method as recited in Claim 95 wherein the disorder is duodenal ulcer disease.

97. (New) The method as recited in Claim 95 wherein the disorder is a gastric ulcer disease.

98. (New) The method as recited in Claim 95 wherein the disorder is gastroesophageal reflux disease (GERD).

99. (New) The method as recited in Claim 95 wherein the disorder is erosive esophagitis.

100. (New) The method as recited in Claim 95 wherein the disorder is poorly responsive symptomatic GERD.

101. (New) The method as recited in Claim 95 wherein the disorder is a pathological hypersecretory disease.

102. (New) The method as recited in Claim 95 wherein the disorder is Zollinger Ellison Syndrome.

103. (New) The method as recited in Claim 95 wherein the disorder is dyspepsia.

104. (New) The method as recited in Claim 95 wherein the PPI is omeprazole.

105. (New) The method as recited in Claim 95 wherein the PPI is lansoprazole.

106. (New) The method as recited in Claim 95 wherein the PPI is rabeprazole.

107. (New) The method as recited in Claim 95 wherein the PPI is esomeprazole.

108. (New) The method as recited in Claim 95 wherein the PPI is pantoprazole.

109. (New) The method as recited in Claim 95 wherein the PPI is pariprazole.

110. (New) The method as recited in Claim 95 wherein the PPI is leminoprazole.

111. (New) The method as recited in Claim 95 wherein the PPI comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

112. (New) The method as recited in Claim 95 wherein the dosage form further comprises a flavoring agent.

113. (New) The method as recited in Claim 95 wherein the dosage form further comprises an anti-foaming agent.

114. (New) The method as recited in Claim 95 wherein the dosage form is a tablet.

115. (New) The method as recited in Claim 95 wherein the dosage form is a powder.

116. (New) The method as recited in Claim 95 wherein the dosage form is a suspension tablet.

117. (New) The method as recited in Claim 95 wherein the dosage form is a chewable tablet.

118. (New) The method as recited in Claim 117 wherein the dosage form further comprises aspartame.

119. (New) The method as recited in Claim 95 wherein the dosage form is a capsule.

120. (New) The method as recited in Claim 95 wherein the dosage form is an effervescent powder.

121. (New) The method as recited in Claim 95 wherein the dosage form is an effervescent tablet.

122. (New) The method as recited in Claim 95 wherein the dosage form is a plurality of pellets.

123. (New) The method as recited in Claim 95 wherein the dosage form is a plurality of granules.

124. (New) The method as recited in Claim 95 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

125. (New) The method as recited in Claim 95 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

126. (New) The method as recited in Claim 95 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

127. (New) The method as recited in Claim 95 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

128. (New) The method as recited in Claim 95 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate, and other magnesium salts.

129. (New) The method as recited in Claim 95 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

130. (New) The method as recited in Claim 95 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

131. (New) The method as recited in Claim 95 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

132. (New) The method as recited in Claim 95 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

133. (New) The method as recited in Claim 95 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

134. (New) The method as recited in Claim 95 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

135. (New) The method as recited in Claim 95 further comprising combining the dosage form with an aqueous medium.

136. (New) The method as recited in Claim 135 wherein the aqueous medium comprises sodium bicarbonate solution.

137. (New) The method as recited in Claim 135 wherein the aqueous medium comprises 8.4% (w/v) sodium bicarbonate solution.

138. (New) The method as recited in Claim 137 wherein the solution is present in an amount of about 10 ml to about 60 ml.

139. (New) The method as recited in Claim 135 wherein the aqueous medium comprises water.

140. (New) The method as recited in Claim 135 wherein the aqueous medium comprises at least one flavoring agent.

141. (New) A composition, comprising:

(a) a proton pump inhibitor (PPI) selected from a group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole and leminoprazole;

(b) gastric secretions; and

(c) at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the PPI by the gastric secretions so as to achieve bioavailability of the PPI in a subject,

wherein the PPI and the buffering agent comprise a solid dosage form, which is capable of disintegration and dissolution in the gastric secretions and is not enteric-coated or delayed-released.

142. (New) The composition as recited in Claim 141 wherein the bioavailability of the PPI is sufficient to elicit a therapeutic effect.

143. (New) The composition as recited in Claim 141 wherein the PPI is present in a therapeutically effective amount.

144. The composition as recited in Claim 141 wherein the PPI comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

145. (New) The composition as recited in Claim 141 wherein the PPI is omeprazole.

146. (New) The composition as recited in Claim 141 wherein the PPI is lansoprazole.

147. (New) The composition as recited in Claim 141 wherein the PPI is rabeprazole.

148. (New) The composition as recited in Claim 141 wherein the PPI is esomeprazole.

149. (New) The composition as recited in Claim 141 wherein the PPI is pantoprazole.

150. (New) The composition as recited in Claim 141 wherein the PPI is pariprazole.

151. (New) The composition as recited in Claim 141 wherein the PPI is leminoprazole.

152. (New) The composition as recited in Claim 141 further comprising a flavoring agent.

153. (New) The composition as recited in Claim 141 further comprising an anti-foaming agent.

154. (New) The composition as recited in Claim 141 wherein the dosage form is a tablet.

155. (New) The composition as recited in Claim 141 wherein the dosage form is a powder.

156. (New) The composition as recited in Claim 141 wherein the dosage form is a suspension tablet.

157. (New) The composition as recited in Claim 141 wherein the dosage form is a chewable tablet.

158. (New) The composition as recited in Claim 157 wherein the dosage form further comprises aspartame.

159. (New) The composition as recited in Claim 141 wherein the dosage form is a capsule.

160. (New) The composition as recited in Claim 141 wherein the dosage form is an effervescent powder.

161. (New) The composition as recited in Claim 141 wherein the dosage form is an effervescent tablet.

162. (New) The composition as recited in Claim 141 wherein the dosage form is a plurality of pellets.

163. (New) The composition as recited in Claim 141 wherein the dosage form is a plurality of granules.

164. (New) The composition as recited in Claim 141 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

165. (New) The composition as recited in Claim 141 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

166. (New) The composition as recited in Claim 141 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

167. (New) The composition as recited in Claim 141 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

168. (New) The composition as recited in Claim 141 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

169. (New) The composition as recited in Claim 141 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

170. (New) The composition as recited in Claim 141 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

171. (New) The composition as recited in Claim 141 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

172. (New) The composition as recited in Claim 141 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

173. (New) The composition as recited in Claim 141 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

174. (New) The composition as recited in Claim 141 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

175. (New) The composition as recited in Claim 141 further comprising a second aqueous medium.

176. (New) The composition as recited in Claim 175 wherein the second aqueous medium is sodium bicarbonate solution.

177. (New) The composition as recited in Claim 175 wherein the second aqueous medium is 8.4% (w/v) sodium bicarbonate solution.

178. (New) The composition as recited in Claim 176 wherein the sodium bicarbonate solution is present in an amount of about 10 ml to about 60 ml.

179. (New) The composition as recited in Claim 175 wherein the second aqueous medium is water.

180. (New) The composition of Claim 179 wherein the water is present in an amount of about 10 ml to about 60 ml.

181. (New) A solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) a first part comprising a proton pump inhibitor (PPI) selected from a group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole and leminoprazole; and

(b) a second part surrounding the first part, the second part comprising at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the PPI by gastric acid so as to achieve bioavailability of the PPI in a subject after oral administration of the dosage form.

182. (New) The dosage form as recited in Claim 181 wherein the bioavailability of the PPI is sufficient to elicit a therapeutic effect.

183. (New) The dosage form as recited in Claim 181 wherein the PPI is present in a therapeutically effective amount.

184. (New) The dosage form as recited in Claim 181 wherein the PPI comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

185. (New) The dosage form as recited in Claim 181 wherein the PPI is omeprazole.

186. (New) The dosage form as recited in Claim 181 wherein the PPI is lansoprazole.

187. (New) The dosage form as recited in Claim 181 wherein the PPI is rabeprazole.

188. (New) The dosage form as recited in Claim 181 wherein the PPI is esomeprazole.

189. (New) The dosage form as recited in Claim 181 wherein the PPI is pantoprazole.

190. (New) The dosage form as recited in Claim 181 wherein the PPI is pariprazole.

191. (New) The dosage form as recited in Claim 181 wherein the PPI is leminoprazole.

192. (New) The dosage form as recited in Claim 181 wherein the first part comprises a compressed tablet.

193. (New) The dosage form as recited in Claim 192 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

194. (New) The dosage form as recited in Claim 181 wherein the first part further comprises a capsule containing the PPI, and the second part further comprises a capsule containing the capsule of the first part.

195. (New) The dosage form as recited in Claim 181 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

196. (New) The dosage form as recited in Claim 181 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

197. (New) The dosage form as recited in Claim 181 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

198. (New) The dosage form as recited in Claim 181 wherein the buffering agent is about 250 mg to about 1680 mg sodium bicarbonate.

199. (New) The dosage form as recited in Claim 181 wherein the buffering agent is about 840 mg to about 1680 mg sodium bicarbonate.

200. (New) The dosage form as recited in Claim 181 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

201. (New) The dosage form as recited in Claim 181 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

202. (New) The dosage form as recited in Claim 181 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

203. (New) A method of treating an acid-related gastrointestinal condition, comprising orally administering to a subject a solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) a first part comprising a proton pump inhibitor (PPI) selected from a group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole and leminoprazole; and

(b) a second part surrounding the first part, the second part comprising at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the PPI by gastric acid so as to achieve bioavailability of the PPI in the subject after oral administration of the dosage form.

204. (New) The method as recited in Claim 203 wherein the disorder is duodenal ulcer disease.

205. (New) The method as recited in Claim 203 wherein the disorder is a gastric ulcer disease.

206. (New) The method as recited in Claim 203 wherein the disorder is gastroesophageal reflux disease (GERD).

207. (New) The method as recited in Claim 203 wherein the disorder is erosive esophagitis.

208. (New) The method as recited in Claim 203 wherein the disorder is poorly responsive symptomatic GERD.

209. (New) The method as recited in Claim 203 wherein the disorder is a pathological hypersecretory disease.

210. (New) The method as recited in Claim 203 wherein the disorder is Zollinger Ellison Syndrome.

211. (New) The method as recited in Claim 203 wherein the disorder is dyspepsia.

212. (New) The method as recited in Claim 203 wherein the PPI is omeprazole.

213. (New) The method as recited in Claim 203 wherein the PPI is lansoprazole.

214. (New) The method as recited in Claim 203 wherein the PPI is rabeprazole.

215. (New) The method as recited in Claim 203 wherein the PPI is esomeprazole.

216. (New) The method as recited in Claim 203 wherein the PPI is pantoprazole.

217. (New) The method as recited in Claim 203 wherein the PPI is pariprazole.

218. (New) The method as recited in Claim 203 wherein the PPI is leminoprazole.

219. (New) The method as recited in Claim 203 wherein the PPI comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

220. (New) The method as recited in Claim 203 wherein the first part comprises a compressed tablet.

221. (New) The method as recited in Claim 220 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

222. (New) The method as recited in Claim 203 wherein the first part further comprises a capsule containing the PPI, and the second part further comprises a capsule containing the capsule of the first part.

223. (New) The method as recited in Claim 203 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

224. (New) The method as recited in Claim 203 wherein the buffering agent is present in an amount of about 7.5 mEq to 15 mEq.

225. (New) The method as recited in Claim 203 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

226. (New) The method as recited in Claim 203 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

227. (New) The method as recited in Claim 203 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate, and other magnesium salts.

228. (New) The method as recited in Claim 203 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

229. (New) The method as recited in Claim 203 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

230. (New) The method as recited in Claim 203 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

231. (New) The method as recited in Claim 203 wherein the buffering agent comprises about 500 to about 1000 mg calcium carbonate.

232. (New) The method as recited in Claim 203 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

233. (New) The method as recited in Claim 203 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium bicarbonate.

234. (New) The method as recited in Claim 203 further comprising combining the dosage form with an aqueous medium prior to administration.

235. (New) The method as recited in Claim 234 wherein the aqueous medium comprises sodium bicarbonate solution.

236. (New) The method as recited in Claim 234 wherein the aqueous medium comprises 8.4% (w/v) sodium bicarbonate solution.

237. (New) The method as recited in Claim 234 wherein the aqueous medium comprises water.

238. (New) A solid pharmaceutical dosage form, comprising:

(a) a first part comprising a proton pump inhibitor (PPI) that is in an enteric-coated or delayed-released form, the PPI selected from a group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole and leminoprazole; and

(b) a second part contacting the first part, the second part comprising at least one buffering agent present in an amount of about 4 mEq to about 30 mEq.

239. (New) The dosage form as recited in Claim 238 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

240. (New) The dosage form as recited in Claim 238 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

241. (New) The dosage form as recited in Claim 238 wherein the bioavailability of the PPI is sufficient to elicit a therapeutic effect.

242. (New) The dosage form as recited in Claim 238 wherein the PPI is present in a therapeutically effective amount.

243. (New) The dosage form as recited in Claim 238 wherein the PPI comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

244. (New) The dosage form as recited in Claim 238 wherein the PPI is omeprazole.

245. (New) The dosage form as recited in Claim 238 wherein the PPI is lansoprazole.

246. (New) The dosage form as recited in Claim 238 wherein the PPI is rabeprazole.

247. (New) The dosage form as recited in Claim 238 wherein the PPI is esomeprazole.

248. (New) The dosage form as recited in Claim 238 wherein the PPI is pantoprazole.

249. (New) The dosage form as recited in Claim 238 wherein the PPI is pariprazole.

250. (New) The dosage form as recited in Claim 238 wherein the PPI is leminoprazole.

251. (New) The dosage form as recited in Claim 238 wherein the PPI comprises enteric coated granules, which surround an inner core of the second part, the second part further comprising a non-enteric-coated PPI.

252. (New) The dosage form as recited in Claim 238 wherein the first part further comprises a non-enteric-coated PPI.

253. (New) The dosage form as recited in Claim 238 wherein the first part further comprises a non-enteric-coated PPI and the second part surrounds the first part.

254. (New) The dosage form as recited in Claim 238 wherein the first part is a tablet.

255. (New) The dosage form as recited in Claim 254 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

256. (New) The dosage form as recited in Claim 238 wherein the first part further comprises a capsule containing the PPI, and the second part further comprises a capsule containing the capsule of the first part.

257. (New) The dosage form as recited in Claim 238 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

258. (New) The dosage form as recited in Claim 238 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

259. (New) The dosage form as recited in Claim 238 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

260. (New) The dosage form as recited in Claim 238 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

261. (New) The dosage form as recited in Claim 238 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

262. (New) The dosage form as recited in Claim 238 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

263. The dosage form as recited in Claim 238 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

264. (New) The dosage form as recited in Claim 238 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

265. (New) The dosage form as recited in Claim 238 wherein the second part surrounds the first part and wherein the second part further comprises non-enteric-coated PPI.

266. (New) A method of treating an acid-related gastrointestinal condition, comprising orally administering to a subject a solid pharmaceutical dosage form, comprising:

(a) a first part comprising a proton pump inhibitor (PPI) that is in an enteric-coated or delayed-released form, the PPI selected from a group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole and leminoprazole; and

(b) a second part contacting the first part, the second part comprising at least one buffering agent present in an amount of about 4 mEq to about 30 mEq.

267. (New) The method as recited in Claim 266 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

268. (New) The method as recited in Claim 266 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

269. (New) The method as recited in Claim 266 wherein the PPI comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

270. (New) The method as recited in Claim 266 wherein the PPI is omeprazole.

271. (New) The method as recited in Claim 266 wherein the PPI is lansoprazole.

272. (New) The method as recited in Claim 266 wherein the PPI is rabeprazole.

273. (New) The method as recited in Claim 266 wherein the PPI is esomeprazole.

274. (New) The method as recited in Claim 266 wherein the PPI is pantoprazole.

275. (New) The method as recited in Claim 266 wherein the PPI is pariprazole.

276. (New) The method as recited in Claim 266 wherein the PPI is leminoprazole.

277. (New) The method as recited in Claim 266 wherein the PPI comprises enteric coated granules, which surround an inner core of the second part, the second part further comprising a non-enteric-coated PPI.

278. (New) The method as recited in Claim 266 wherein the first part further comprises a non-enteric-coated PPI.

279. (New) The method as recited in Claim 266 wherein the first part further comprises a non-enteric-coated PPI and the second part surrounds the first part.

280. (New) The method as recited in Claim 266 wherein the first part is a tablet.

281. (New) The method as recited in Claim 280 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

282. (New) The method as recited in Claim 266 wherein the first part further comprises a capsule containing the PPI, and the second part further comprises a capsule containing the capsule of the first part.

283. (New) The method as recited in Claim 266 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

284. (New) The method as recited in Claim 266 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate, and other magnesium salts.

285. (New) The method as recited in Claim 266 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

286. (New) The method as recited in Claim 266 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

287. (New) The method as recited in Claim 266 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

288. (New) The method as recited in Claim 266 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

289. The method as recited in Claim 266 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

290. (New) The method as recited in Claim 266 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

291. (New) The method as recited in Claim 266 wherein the second part surrounds the first part and wherein the second part further comprises non-enteric-coated PPI.

292. (New) A solid pharmaceutical composition, comprising:

(a) omeprazole; and

(b) at least one buffering agent that is not an amino acid, wherein the buffering agent is present in an amount of at least 30 parts to 1 part omeprazole.

293. (New) The composition as recited in Claim 292 wherein the omeprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base salt thereof.

294. (New) The composition as recited in Claim 292 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

295. (New) The composition as recited in Claim 292 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate, and other magnesium salts.

296. (New) The composition as recited in Claim 292 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

297. (New) The composition as recited in Claim 292 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

298. (New) The composition as recited in Claim 292 further comprising a flavoring agent.

299. (New) The composition as recited in Claim 292 further comprising an anti-foaming agent.

300. (New) A solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) omeprazole; and

(b) at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the omeprazole by gastric acid so as to achieve bioavailability of the omeprazole in a subject after oral administration of the dosage form.

301. (New) The dosage form as recited in Claim 300 wherein the omeprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

302. (New) The dosage form as recited in Claim 300 further comprising a flavoring agent.

303. (New) The dosage form as recited in Claim 300 further comprising an anti-foaming agent.

304. (New) The dosage form as recited in Claim 300 wherein the omeprazole is present in a therapeutically effective amount.

305. (New) The dosage form as recited in Claim 300 wherein the omeprazole is present in an amount of about 10 mg to about 40 mg.

306. (New) The dosage form as recited in Claim 300 wherein the dosage form is a tablet.

307. (New) The dosage form as recited in Claim 300 wherein the dosage form is a powder.

308. (New) The dosage form as recited in Claim 300 wherein the dosage form is a suspension tablet.

309. (New) The dosage form as recited in Claim 300 wherein the dosage form is a chewable tablet.

310. (New) The dosage form as recited in Claim 309 further comprising aspartame.

311. (New) The dosage form as recited in Claim 300 wherein the dosage form is a capsule.

312. (New) The dosage form as recited in Claim 300 wherein the dosage form is an effervescent powder.

313. (New) The dosage form as recited in Claim 300 wherein the dosage form is an effervescent tablet.

314. (New) The dosage form as recited in Claim 300 wherein the dosage form is a plurality of pellets.

315. (New) The dosage form as recited in Claim 300 wherein the dosage form is a plurality of granules.

316. (New) The dosage form as recited in Claim 300 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

317. (New) The dosage form as recited in Claim 300 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

318. (New) The dosage form as recited in Claim 300 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

319. (New) The dosage form as recited in Claim 300 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

320. (New) The dosage form as recited in Claim 300 wherein the buffering agent comprises sodium bicarbonate.

321. (New) The dosage form as recited in Claim 300 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

322. (New) The dosage form as recited in Claim 300 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

323. (New) The dosage form as recited in Claim 300 wherein the buffering agent comprises calcium carbonate.

324. (New) The dosage form as recited in Claim 300 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

325. (New) The dosage form as recited in Claim 300 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

326. (New) The dosage form as recited in Claim 300 wherein the buffering agent comprises a combination of calcium carbonate and sodium bicarbonate.

327. (New) The dosage form as recited in Claim 300 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

328. (New) The dosage form as recited in Claim 302 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

329. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 300 with an aqueous medium.

330. (New) The liquid pharmaceutical composition of Claim 329 wherein the aqueous medium comprises sodium bicarbonate solution.

331. (New) The liquid pharmaceutical composition of Claim 329 wherein the aqueous medium comprises gastric secretions.

332. (New) The liquid pharmaceutical composition of Claim 329 wherein the aqueous medium comprises water.

333. (New) The liquid pharmaceutical composition as recited in Claim 329 wherein the dosage form is a powder and the aqueous medium is water.

334. (New) The liquid pharmaceutical composition as recited in Claim 329 wherein the dosage form is a plurality of granules and the aqueous medium is water.

335. (New) A method of treating an acid-related gastrointestinal condition, comprising orally administering to a subject a solid pharmaceutical dosage form to a subject that is not enteric-coated or delayed-released, comprising:

(a) omeprazole; and

(b) at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the omeprazole by gastric acid so as to achieve bioavailability of the omeprazole in the subject after oral administration of the dosage form.

336. (New) The method as recited in Claim 335 wherein the disorder is duodenal ulcer disease.

337. (New) The method as recited in Claim 335 wherein the disorder is a gastric ulcer disease.

338. (New) The method as recited in Claim 335 wherein the disorder is gastroesophageal reflux disease (GERD).

339. (New) The method as recited in Claim 335 wherein the disorder is erosive esophagitis.

340. (New) The method as recited in Claim 335 wherein the disorder is poorly responsive symptomatic GERD.

341. (New) The method as recited in Claim 335 wherein the disorder is a pathological hypersecretory disease.

342. (New) The method as recited in Claim 335 wherein the disorder is Zollinger Ellison Syndrome.

343. (New) The method as recited in Claim 335 wherein the disorder is dyspepsia.

344. (New) The method as recited in Claim 335 wherein the omeprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

345. (New) The method as recited in Claim 335 wherein the dosage form further comprises a flavoring agent.

346. (New) The method as recited in Claim 335 wherein the dosage form further comprises an anti-foaming agent.

347. (New) The method as recited in Claim 335 wherein the omeprazole is present in an amount of about 10 mg to about 40 mg.

348. (New) The method as recited in Claim 335 wherein the dosage form is a tablet.

349. (New) The method as recited in Claim 335 wherein the dosage form is a powder.

350. (New) The method as recited in Claim 335 wherein the dosage form is a suspension tablet.

351. (New) The method as recited in Claim 335 wherein the dosage form is a chewable tablet.

352. (New) The method as recited in Claim 351 wherein the chewable table further comprises aspartame.

353. (New) The method as recited in Claim 335 wherein the dosage form is a capsule.

354. (New) The method as recited in Claim 335 wherein the dosage form is an effervescent powder.

355. (New) The method as recited in Claim 335 wherein the dosage form is an effervescent tablet.

356. (New) The method as recited in Claim 335 wherein the dosage form is a plurality of pellets.

357. (New) The method as recited in Claim 335 wherein the dosage form is a plurality of granules.

358. (New) The method as recited in Claim 335 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

359. (New) The method as recited in Claim 335 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

360. (New) The method as recited in Claim 335 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

361. (New) The method as recited in Claim 335 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

362. (New) The method as recited in Claim 335 wherein the buffering agent comprises sodium bicarbonate.

363. (New) The method as recited in Claim 335 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

364. (New) The method as recited in Claim 335 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

365. (New) The method as recited in Claim 335 wherein the buffering agent comprises calcium carbonate.

366. (New) The method as recited in Claim 335 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

367. (New) The method as recited in Claim 335 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

368. (New) The method as recited in Claim 335 wherein the buffering agent comprises a combination of calcium carbonate and sodium bicarbonate.

369. (New) The method as recited in Claim 335 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

370. (New) The method as recited in Claim 335 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

371. (New) A composition, comprising:

(a) omeprazole;

(b) gastric secretions; and

(c) at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the omeprazole by the gastric secretions so as to achieve bioavailability of the omeprazole in a subject,

wherein the omeprazole and the buffering agent comprise a solid dosage form, which is capable of disintegration and dissolution in the gastric secretions and is not enteric-coated or delayed-released.

372. (New) The composition as recited in Claim 371 wherein the omeprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

373. (New) The composition as recited in Claim 371 wherein the omeprazole is present in a therapeutically effective amount.

374. (New) The composition as recited in Claim 371 wherein the omeprazole is present in an amount of about 10 mg to about 40 mg.

375. (New) The composition as recited in Claim 371 wherein the dosage form is a tablet.

376. (New) The composition as recited in Claim 371 wherein the dosage form is a powder.

377. (New) The composition as recited in Claim 371 wherein the dosage form is a suspension tablet.

378. (New) The composition as recited in Claim 371 wherein the dosage form is a chewable tablet.

379. (New) The composition as recited in Claim 378 wherein the chewable tablet further comprises aspartame.

380. (New) The composition as recited in Claim 371 wherein the dosage form is a capsule.

381. (New) The composition as recited in Claim 371 wherein the dosage form is an effervescent powder.

382. (New) The composition as recited in Claim 371 wherein the dosage form is an effervescent tablet.

383. (New) The composition as recited in Claim 371 wherein the dosage form is a plurality of pellets.

384. (New) The composition as recited in Claim 371 wherein the dosage form is a plurality of granules.

385. (New) The composition as recited in Claim 371 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

386. (New) The composition as recited in Claim 371 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

387. (New) The composition as recited in Claim 371 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

388. (New) The composition as recited in Claim 371 wherein the buffering agent comprises sodium bicarbonate.

389. (New) The composition as recited in Claim 371 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

390. (New) The composition as recited in Claim 371 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

391. (New) The composition as recited in Claim 371 wherein the buffering agent comprises calcium carbonate.

392. (New) The composition as recited in Claim 371 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

393. (New) The composition as recited in Claim 371 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

394. (New) The composition as recited in Claim 371 wherein the buffering agent comprises a combination of calcium carbonate and sodium bicarbonate.

395. (New) The composition as recited in Claim 371 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

396. (New) The composition as recited in Claim 371 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

397. (New) The composition as recited in Claim 371 further comprising a flavoring agent.

398. (New) The composition as recited in Claim 371 further comprising an anti-foaming agent.

399. (New) A solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) a first part comprising omeprazole; and

(b) a second part surrounding the first part, the second part comprising at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the omeprazole by gastric acid so as to achieve bioavailability of the omeprazole in a subject after oral administration of the dosage form.

400. (New) The dosage form as recited in Claim 399 wherein the bioavailability of the omeprazole is sufficient to elicit a therapeutic effect.

401. (New) The dosage form as recited in Claim 399 wherein the omeprazole is present in a therapeutically effective amount.

402. (New) The dosage form as recited in Claim 399 wherein the omeprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

403. (New) The dosage form as recited in Claim 399 wherein the first part comprises a compressed tablet.

404. (New) The dosage form as recited in Claim 403 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

405. (New) The dosage form as recited in Claim 399 wherein the first part further comprises a capsule containing the omeprazole and the second part further comprises a capsule containing the capsule of the first part.

406. (New) The dosage form as recited in Claim 399 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

407. (New) The dosage form as recited in Claim 399 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

408. (New) The dosage form as recited in Claim 399 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

409. (New) The dosage form as recited in Claim 399 wherein the buffering agent is about 250 mg to about 1680 mg sodium bicarbonate.

410. (New) The dosage form as recited in Claim 399 wherein the buffering agent is about 840 mg to about 1680 mg sodium bicarbonate.

411. (New) The dosage form as recited in Claim 399 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

412. (New) The dosage form as recited in Claim 399 wherein the buffering agent is about 500 mg to about 100 mg calcium carbonate.

413. (New) The dosage form as recited in Claim 399 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

414. (New) A method of treating an acid-related gastrointestinal condition, comprising orally administering to a subject a solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) a first part comprising omeprazole; and

(b) a second part surrounding the first part, the second part comprising at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the omeprazole by gastric acid so as to achieve bioavailability of the omeprazole in the subject after oral administration of the dosage form.

415. (New) The method as recited in Claim 414 wherein the disorder is duodenal ulcer disease.

416. (New) The method as recited in Claim 414 wherein the disorder is a gastric ulcer disease.

417. (New) The method as recited in Claim 414 wherein the disorder is gastroesophageal reflux disease (GERD).

418. (New) The method as recited in Claim 414 wherein the disorder is erosive esophagitis.

419. (New) The method as recited in Claim 414 wherein the disorder is poorly responsive symptomatic GERD.

420. (New) The method as recited in Claim 414 wherein the disorder is a pathological hypersecretory disease.

421. (New) The method as recited in Claim 414 wherein the disorder is Zollinger Ellison Syndrome.

422. (New) The method as recited in Claim 414 wherein the disorder is dyspepsia.

423. (New) The method as recited in Claim 414 wherein the omeprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

424. (New) The method as recited in Claim 414 wherein the first part comprises a compressed tablet.

425. (New) The method as recited in Claim 424 wherein the second part further comprises a capsule which comprises the buffering agent and the tablet.

426. (New) The method as recited in Claim 414 wherein the first part further comprises a capsule containing the omeprazole, and the second part further comprises a capsule containing the capsule of the first part.

427. (New) The method as recited in Claim 414 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

428. (New) The method as recited in Claim 414 wherein the buffering agent is present in an amount of about 7.5 mEq to 15 mEq.

429. (New) The method as recited in Claim 414 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

430. (New) A solid pharmaceutical dosage form, comprising:

(a) a first part comprising omeprazole that is in an enteric-coated or delayed-released form; and

(b) a second part contacting the first part, the second part comprising at least one buffering agent present in an amount of about 4 mEq to about 30 mEq.

431. (New) The dosage form as recited in Claim 430 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

432. (New) The dosage form as recited in Claim 430 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

433. (New) The dosage form as recited in Claim 430 wherein the bioavailability of the omeprazole is sufficient to elicit a therapeutic effect.

434. (New) The dosage form as recited in Claim 430 wherein the omeprazole is present in a therapeutically effective amount.

435. (New) The dosage form as recited in Claim 430 wherein the omeprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

436. (New) The dosage form as recited in Claim 430 wherein the omeprazole comprises enteric coated granules, which surround an inner core of the second part, the second part further comprising a non-enteric-coated omeprazole.

437. (New) The dosage form as recited in Claim 430 wherein the first part further comprises a non-enteric-coated omeprazole.

438. (New) The dosage form as recited in Claim 430 wherein the first part further comprises a non-enteric-coated omeprazole and the second part surrounds the first part.

439. (New) The dosage form as recited in Claim 430 wherein the first part is a tablet.

440. (New) The dosage form as recited in Claim 439 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

441. (New) The dosage form as recited in Claim 430 wherein the first part further comprises a capsule containing the omeprazole, and the second part further comprises a capsule containing the capsule of the first part.

442. (New) The dosage form as recited in Claim 430 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

443. (New) The dosage form as recited in Claim 430 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

444. (New) The dosage form as recited in Claim 430 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

445. The dosage form as recited in Claim 430 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

446. (New) The dosage form as recited in Claim 430 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

447. (New) The dosage form as recited in Claim 430 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

448. (New) The dosage form as recited in Claim 430 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

449. (New) The dosage form as recited in Claim 430 wherein the second part surrounds the first part and wherein the second part further comprises non-enteric-coated omeprazole.

450. (New) A method of treating an acid-related gastrointestinal condition, comprising orally administering to a subject a solid pharmaceutical dosage form, comprising:

(a) a first part comprising omeprazole that is in an enteric-coated or delayed-released form; and

(b) a second part contacting the first part, the second part comprising at least one buffering agent present in an amount of about 4 mEq to about 30 mEq.

451. (New) The method as recited in Claim 450 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

452. (New) The method as recited in Claim 450 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

453. (New) The method as recited in Claim 450 wherein the omeprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

454. (New) The method as recited in Claim 450 wherein the omeprazole comprises enteric coated granules, which surround an inner core of the second part, the second part further comprising a non-enteric-coated omeprazole.

455. (New) The method as recited in Claim 450 wherein the first part further comprises a non-enteric-coated omeprazole.

456. (New) The method as recited in Claim 450 wherein the first part further comprises a non-enteric-coated omeprazole and the second part surrounds the first part.

457. (New) The method as recited in Claim 450 wherein the first part is a tablet.

458. (New) The method as recited in Claim 457 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

459. (New) The method as recited in Claim 450 wherein the first part further comprises a capsule containing the omeprazole, and the second part further comprises a capsule containing the capsule of the first part.

460. (New) The method as recited in Claim 450 wherein the second part surrounds the first part and wherein the second part further comprises non-enteric-coated omeprazole.

461. (New) A solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) lansoprazole; and

(b) at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the lansoprazole by gastric acid so as to achieve bioavailability of the lansoprazole in a subject after oral administration of the dosage form.

462. (New) The dosage form as recited in Claim 461 wherein the lansoprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

463. (New) The dosage form as recited in Claim 461 further comprising a flavoring agent.

464. (New) The dosage form as recited in Claim 461 further comprising an anti-foaming agent.

465. (New) The dosage form as recited in Claim 461 wherein the lansoprazole is present in a therapeutically effective amount.

466. (New) The dosage form as recited in Claim 461 wherein the lansoprazole is present in an amount of about 10 mg to about 60 mg.

467. (New) The dosage form as recited in Claim 461 wherein the dosage form is a tablet.

468. (New) The dosage form as recited in Claim 461 wherein the dosage form is a powder.

469. (New) The dosage form as recited in Claim 461 wherein the dosage form is a suspension tablet.

470. (New) The dosage form as recited in Claim 461 wherein the dosage form is a chewable tablet.

471. (New) The dosage form as recited in Claim 470 further comprising aspartame.

472. (New) The dosage form as recited in Claim 461 wherein the dosage form is a capsule.

473. (New) The dosage form as recited in Claim 461 wherein the dosage form is an effervescent powder.

474. (New) The dosage form as recited in Claim 461 wherein the dosage form is an effervescent tablet.

475. (New) The dosage form as recited in Claim 461 wherein the dosage form is a plurality of pellets.

476. (New) The dosage form as recited in Claim 461 wherein the dosage form is a plurality of granules.

477. (New) The dosage form as recited in Claim 461 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

478. (New) The dosage form as recited in Claim 461 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

479. (New) The dosage form as recited in Claim 461 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

480. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

481. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises sodium bicarbonate.

482. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

483. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

484. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises calcium carbonate.

485. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

486. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

487. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises a combination of calcium carbonate and sodium bicarbonate.

488. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

489. (New) The dosage form as recited in Claim 461 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

490. (New) A liquid pharmaceutical composition produced by the method of combining the dosage form recited in Claim 461 with an aqueous medium.

491. (New) The liquid pharmaceutical composition of Claim 490 wherein the aqueous medium comprises sodium bicarbonate solution.

492. (New) The liquid pharmaceutical composition of Claim 490 wherein the aqueous medium comprises gastric secretions.

493. (New) The liquid pharmaceutical composition of Claim 490 wherein the aqueous medium comprises water.

494. (New) The liquid pharmaceutical composition as recited in Claim 490 wherein the dosage form is a powder and the aqueous medium is water.

495. (New) The liquid pharmaceutical composition as recited in Claim 490 wherein the dosage form is a plurality of granules and the aqueous medium is water.

496. (New) A method of treating an acid-related gastrointestinal condition, comprising orally administering to a subject a solid pharmaceutical dosage form to a subject that is not enteric-coated or delayed-released, comprising:

(a) lansoprazole; and

(b) at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the lansoprazole by gastric acid so as to achieve bioavailability of the lansoprazole in the subject after oral administration of the dosage form.

497. (New) The method as recited in Claim 496 wherein the disorder is duodenal ulcer disease.

498. (New) The method as recited in Claim 496 wherein the disorder is a gastric ulcer disease.

499. (New) The method as recited in Claim 496 wherein the disorder is gastroesophageal reflux disease (GERD).

500. (New) The method as recited in Claim 496 wherein the disorder is erosive esophagitis.

501. (New) The method as recited in Claim 496 wherein the disorder is poorly responsive symptomatic GERD.

502. (New) The method as recited in Claim 496 wherein the disorder is a pathological hypersecretory disease.

503. (New) The method as recited in Claim 496 wherein the disorder is Zollinger Ellison Syndrome.

504. (New) The method as recited in Claim 496 wherein the disorder is dyspepsia.

505. (New) The method as recited in Claim 496 wherein the lansoprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

506. (New) The method as recited in Claim 496 wherein the dosage form further comprises a flavoring agent.

507. (New) The method as recited in Claim 496 wherein the dosage form further comprises an anti-foaming agent.

508. (New) The method as recited in Claim 496 wherein the lansoprazole is present in an amount of about 10 mg to about 60 mg.

509. (New) The method as recited in Claim 496 wherein the dosage form is a tablet.

510. (New) The method as recited in Claim 496 wherein the dosage form is a powder.

511. (New) The method as recited in Claim 496 wherein the dosage form is a suspension tablet.

512. (New) The method as recited in Claim 496 wherein the dosage form is a chewable tablet.

513. (New) The method as recited in Claim 512 wherein the chewable table further comprises aspartame.

514. (New) The method as recited in Claim 496 wherein the dosage form is a capsule.

515. (New) The method as recited in Claim 496 wherein the dosage form is an effervescent powder.

516. (New) The method as recited in Claim 496 wherein the dosage form is an effervescent tablet.

517. (New) The method as recited in Claim 496 wherein the dosage form is a plurality of pellets.

518. (New) The method as recited in Claim 496 wherein the dosage form is a plurality of granules.

519. (New) The method as recited in Claim 496 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

520. (New) The method as recited in Claim 496 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

521. (New) The method as recited in Claim 496 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

522. (New) The method as recited in Claim 496 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

523. (New) The method as recited in Claim 496 wherein the buffering agent comprises sodium bicarbonate.

524. (New) The method as recited in Claim 496 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

525. (New) The method as recited in Claim 496 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

526. (New) The method as recited in Claim 496 wherein the buffering agent comprises calcium carbonate.

527. (New) The method as recited in Claim 496 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

528. (New) The method as recited in Claim 496 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

529. (New) The method as recited in Claim 496 wherein the buffering agent comprises a combination of calcium carbonate and sodium bicarbonate.

530. (New) The method as recited in Claim 496 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

531. (New) The method as recited in Claim 496 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

532. (New) A composition, comprising:

(a) lansoprazole;

(b) gastric secretions; and

(c) at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the lansoprazole by the gastric secretions so as to achieve bioavailability of the lansoprazole in a subject,

wherein the lansoprazole and the buffering agent comprise a solid dosage form, which is capable of disintegration and dissolution in the gastric secretions and is not enteric-coated or delayed-released.

533. (New) The composition as recited in Claim 532 wherein the lansoprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

534. (New) The composition as recited in Claim 532 wherein the lansoprazole is present in a therapeutically effective amount.

535. (New) The composition as recited in Claim 532 wherein the lansoprazole is present in an amount of about 10 mg to about 60 mg.

536. (New) The composition as recited in Claim 532 wherein the dosage form is a tablet.

537. (New) The composition as recited in Claim 532 wherein the dosage form is a powder.

538. (New) The composition as recited in Claim 532 wherein the dosage form is a suspension tablet.

539. (New) The composition as recited in Claim 532 wherein the dosage form is a chewable tablet.

540. (New) The composition as recited in Claim 539 wherein the chewable tablet further comprises aspartame.

541. (New) The composition as recited in Claim 532 wherein the dosage form is a capsule.

542. (New) The composition as recited in Claim 532 wherein the dosage form is an effervescent powder.

543. (New) The composition as recited in Claim 532 wherein the dosage form is an effervescent tablet.

544. (New) The composition as recited in Claim 532 wherein the dosage form is a plurality of pellets.

545. (New) The composition as recited in Claim 532 wherein the dosage form is a plurality of granules.

546. (New) The composition as recited in Claim 532 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

547. (New) The composition as recited in Claim 532 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

548. (New) The composition as recited in Claim 532 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

549. (New) The composition as recited in Claim 532 wherein the buffering agent comprises sodium bicarbonate.

550. (New) The composition as recited in Claim 532 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

551. (New) The composition as recited in Claim 532 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

552. (New) The composition as recited in Claim 532 wherein the buffering agent comprises calcium carbonate.

553. (New) The composition as recited in Claim 532 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

554. (New) The composition as recited in Claim 532 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

555. (New) The composition as recited in Claim 532 wherein the buffering agent comprises a combination of calcium carbonate and sodium bicarbonate.

556. (New) The composition as recited in Claim 532 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

557. (New) The composition as recited in Claim 532 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

558. (New) The composition as recited in Claim 532 further comprising a flavoring agent.

559. (New) The composition as recited in Claim 532 further comprising an anti-foaming agent.

560. (New) A solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) a first part comprising lansoprazole; and

(b) a second part surrounding the first part, the second part comprising at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the lansoprazole by gastric acid so as to achieve bioavailability of the lansoprazole in a subject after oral administration of the dosage form.

561. (New) The dosage form as recited in Claim 560 wherein the bioavailability of the lansoprazole is sufficient to elicit a therapeutic effect.

562. (New) The dosage form as recited in Claim 560 wherein the lansoprazole is present in a therapeutically effective amount.

563. (New) The dosage form as recited in Claim 560 wherein the lansoprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

564. (New) The dosage form as recited in Claim 560 wherein the first part comprises a compressed tablet.

565. (New) The dosage form as recited in Claim 564 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

566. (New) The dosage form as recited in Claim 560 wherein the first part further comprises a capsule containing the lansoprazole and the second part further comprises a capsule containing the capsule of the first part.

567. (New) The dosage form as recited in Claim 560 wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

568. (New) The dosage form as recited in Claim 560 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

569. (New) The dosage form as recited in Claim 560 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

570. (New) The dosage form as recited in Claim 560 wherein the buffering agent is about 250 mg to about 1680 mg sodium bicarbonate.

571. (New) The dosage form as recited in Claim 560 wherein the buffering agent is about 840 mg to about 1680 mg sodium bicarbonate.

572. (New) The dosage form as recited in Claim 560 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

573. (New) The dosage form as recited in Claim 560 wherein the buffering agent is about 500 mg to about 100 mg calcium carbonate.

574. (New) The dosage form as recited in Claim 560 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

575. (New) A method of treating an acid-related gastrointestinal condition, comprising orally administering to a subject a solid pharmaceutical dosage form that is not enteric-coated or delayed-released, comprising:

(a) a first part comprising lansoprazole; and

(b) a second part surrounding the first part, the second part comprising at least one buffering agent present in an amount sufficient to prevent or inhibit acid degradation of the lansoprazole by gastric acid so as to achieve bioavailability of the lansoprazole in the subject after oral administration of the dosage form.

576. (New) The method as recited in Claim 575 wherein the disorder is duodenal ulcer disease.

577. (New) The method as recited in Claim 575 wherein the disorder is a gastric ulcer disease.

578. (New) The method as recited in Claim 575 wherein the disorder is gastroesophageal reflux disease (GERD).

579. (New) The method as recited in Claim 575 wherein the disorder is erosive esophagitis.

580. (New) The method as recited in Claim 575 wherein the disorder is poorly responsive symptomatic GERD.

581. (New) The method as recited in Claim 575 wherein the disorder is a pathological hypersecretory disease.

582. (New) The method as recited in Claim 575 wherein the disorder is Zollinger Ellison Syndrome.

583. (New) The method as recited in Claim 575 wherein the disorder is dyspepsia.

584. (New) The method as recited in Claim 575 wherein the lansoprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

585. (New) The method as recited in Claim 575 wherein the first part comprises a compressed tablet.

586. (New) The method as recited in Claim 585 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

587. (New) The method as recited in Claim 575 wherein the first part further comprises a capsule containing the lansoprazole, and the second part further comprises a capsule containing the capsule of the first part.

588. (New) The method as recited in Claim 575 wherein the buffering agent is present in an amount of about 4 mEq to about 30 mEq.

589. (New) The method as recited in Claim 575 wherein the buffering agent is present in an amount of about 7.5 mEq to 15 mEq.

590. (New) The method as recited in Claim 575 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

591. (New) A solid pharmaceutical dosage form, comprising:

(a) a first part comprising lansoprazole that is in an enteric-coated or delayed-released form; and

(b) a second part contacting the first part, the second part comprising at least one buffering agent present in an amount of about 4 mEq to about 30 mEq.

592. (New) The dosage form as recited in Claim 591 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

593. (New) The dosage form as recited in Claim 591 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

594. (New) The dosage form as recited in Claim 591 wherein the bioavailability of the lansoprazole is sufficient to elicit a therapeutic effect.

595. (New) The dosage form as recited in Claim 591 wherein the lansoprazole is present in a therapeutically effective amount.

596. (New) The dosage form as recited in Claim 591 wherein the lansoprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

597. (New) The dosage form as recited in Claim 591 wherein the lansoprazole comprises enteric coated granules, which surround an inner core of the second part, the second part further comprising a non-enteric-coated lansoprazole.

598. (New) The dosage form as recited in Claim 591 wherein the first part further comprises a non-enteric-coated lansoprazole.

599. (New) The dosage form as recited in Claim 591 wherein the first part further comprises a non-enteric-coated lansoprazole and the second part surrounds the first part.

600. (New) The dosage form as recited in Claim 591 wherein the first part is a tablet.

601. (New) The dosage form as recited in Claim 600 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

602. (New) The dosage form as recited in Claim 600 wherein the first part further comprises a capsule containing the lansoprazole, and the second part further comprises a capsule containing the capsule of the first part.

603. (New) The dosage form as recited in Claim 600 wherein the buffering agent comprises about 250 mg to about 1680 mg sodium bicarbonate.

604. (New) The dosage form as recited in Claim 600 wherein the buffering agent comprises about 840 mg to about 1680 mg sodium bicarbonate.

605. (New) The dosage form as recited in Claim 600 wherein the buffering agent comprises about 250 mg to about 1000 mg calcium carbonate.

606. The dosage form as recited in Claim 600 wherein the buffering agent comprises about 500 mg to about 1000 mg calcium carbonate.

607. (New) The dosage form as recited in Claim 600 wherein the buffering agent comprises a combination of sodium bicarbonate and calcium carbonate.

608. (New) The dosage form as recited in Claim 600 wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, magnesium silicate, magnesium lactate and other magnesium salts.

609. (New) The dosage form as recited in Claim 600 wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, calcium glycinate, calcium maleate, and other calcium salts.

610. (New) The dosage form as recited in Claim 600 wherein the second part surrounds the first part and wherein the second part further comprises non-enteric-coated lansoprazole.

611. (New) A method of treating an acid-related gastrointestinal condition, comprising orally administering to a subject a solid pharmaceutical dosage form, comprising:

(a) a first part comprising lansoprazole that is in an enteric-coated or delayed-released form; and

(b) a second part contacting the first part, the second part comprising at least one buffering agent present in an amount of about 4 mEq to about 30 mEq.

612. (New) The method as recited in Claim 611 wherein the buffering agent is present in an amount of about 7.5 mEq to about 15 mEq.

613. (New) The method as recited in Claim 611 wherein the buffering agent is present in an amount of about 10 mEq to about 20 mEq.

614. (New) The method as recited in Claim 611 wherein the lansoprazole comprises a substantially pure enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

615. (New) The method as recited in Claim 611 wherein the lansoprazole comprises enteric coated granules, which surround an inner core of the second part, the second part further comprising a non-enteric-coated lansoprazole.

616. (New) The method as recited in Claim 611 wherein the first part further comprises a non-enteric-coated lansoprazole.

617. (New) The method as recited in Claim 611 wherein the first part further comprises a non-enteric-coated lansoprazole and the second part surrounds the first part.

618. (New) The method as recited in Claim 611 wherein the first part is a tablet.

619. (New) The method as recited in Claim 618 wherein the second part further comprises a capsule which surrounds the buffering agent and the tablet.

620. (New) The method as recited in Claim 611 wherein the first part further comprises a capsule containing the lansoprazole, and the second part further comprises a capsule containing the capsule of the first part.

621. (New) The method as recited in Claim 611 wherein the second part surrounds the first part and wherein the second part further comprises non-enteric-coated lansoprazole.

REMARKS:

Claims 1, 4-7, and 9-15 are pending in this application and stand rejected. Claims 23-621 are newly added in substitution of the rejected claims. The support for these claims are detailed in the table at the end of these Remarks. Applicant respectfully submits that no new matter has been added by way of this amendment.

Applicant thanks the Examiner for the interview of April 9, 2001. As requested during the interview, Applicant has obtained English translations of Japanese Patent Applications Nos. 05255088 and 05194225, which are included in a Supplemental Information Disclosure Statement that will be hand delivered to the Examiner in the next several days. Applicant is also providing the Examiner with a complete set of references cited in previous information disclosure statements, which the Examiner informed Applicant were misplaced by the PTO.

As established below, Applicant submits that the new claims are patentable over the prior art.

Rejections Under 35 U.S.C. §102(b)

The Examiner rejected now cancelled claims 7,10 and 12 as being anticipated by Lovgren et al. U.S. Patent No. 4,786,505 or by Ooishi et al. Japanese Patent Application No. 05255088. However, Applicant's new Claims 23 – 621 to pharmaceutical dosage forms and compositions are not anticipated by these references, nor by Ooishi et al. Japanese Patent Application No. 05194225. These references are directed to formulating intermediate cores, which are converted to enteric coated dosage forms—not to dosage forms that release the PPI in the stomach as claimed by Applicant. The dosage forms and compositions of Claims 23-237; 292-429 and 461-590 of the present invention are free of enteric coatings and therefore are not shielded from interacting with gastric acid secretions, and are specifically designed for disintegration and

dissolution in the stomach whereas the enteric forms disintegrate and dissolve in the duodenum. The dosage forms of Claims 238-291; 430-460 and 591-621 employ enteric-coated PPI (and optionally non-enteric-coated PPI) with a non-enteric-coated buffering agent in an amount of about 4 mEq to about 30 mEq. These forms have the dual action of release of buffer (and non-enteric-coated PPI if it is also used) in the stomach for an antacid effect, and release of enteric-coated PPI in the duodenum. The advantages of the inventive forms over the enteric-coated forms of the prior art are stated at pages 32-41 and 66 of the specification and include more rapid drug absorption, and an antacid effect by the buffering agent.

Importantly, none of the cited references teach the oral administration of the uncoated intermediate cores, nor do the cores meet the limitations of the Claims. The intermediate cores, therefore, are not "dosage forms" as claimed because a "dosage form" is defined as a completed form of a pharmaceutical preparation. Dorland's Medical Dictionary, 26th Ed. p. 218 (1988). Consequently, there is no teaching that such intermediate cores interact with gastric secretions to form the composition as claimed by Applicant. Indeed, the prior art teaches that such cores must have enteric coatings.

More specifically, the Lovgren '505 Patent teaches enteric coated forms having central cores with alkaline reacting substances to create a "micro-pH" around each omeprazole particle to protect the acid labile omeprazole from the acidic enteric coating polymers used to make the finished dosage forms. Lovgren '505 Patent, columns 3-5. Lovgren emphasizes that due to the instability of omeprazole in acidic and neutral media, "an oral dosage form of omeprazole must be protected from contact with the acid reacting gastric juices in order to reach the small intestine without degradation." Col. 1, ln. 35-39. The protection referred to by Lovgren is enteric coatings—not the buffering systems of the present invention. Indeed, Lovgren states: "In order

to obtain a pharmaceutical dosage form of omeprazole which prevents omeprazole from contact with acidic gastric juice, the cores **must** be enteric coated." Col. 1, ln. 48-51 (emphasis added). Further teaching away from the present invention, Lovgren states:

> If a conventional formulation of omeprazole is made, the stability is not satisfactory, particularly in resistance to humidity, and special moisture-proof packing has been adopted to minimize the troubles. However, this provides no satisfactory solution to the problems in today's drug distribution system, and also leads to increased costs. Under the circumstances, there has been a demand for the development of new enteric preparations of omeprazole with better stability.

Col. 2, ln. 14-23.

The "final dosage form" of Lovgren is "either an enteric coated tablet or capsule or in the case of enteric coated pellets, pellets dispensed in hard gelatin capsules or sachets or pellets formulated into tablets." Col. 5, ln. 60-64. Thus, the Lovgren '505 Patent does not teach dosage forms free of enteric coatings that interact with gastric acid secretions.

At the April 9th interview, the intermediate cores of the Lovgren '505 Patent were discussed in the context of Applicant's then pending claims to a pharmaceutical composition of a PPI and a buffer. As such, the Examiner requested Applicant to detail the amounts of the buffering agents taught by Lovgren. Applicant has done so below, and submits that Lovgren does not anticipate Applicant's new claims because they are directed to dosage forms employing significantly more buffer than that disclosed by Lovgren, and to compositions also comprising gastric acid secretions, a flavoring agent, an anti-foaming agent and buffer combinations.

The amount of buffering agent employed is critical to the ultimate bioavailability of the proton pump inhibitor (PPI). Without the benefit of the protection of an enteric coating, the buffering agent must be present in an amount sufficient to prevent or inhibit acid degradation of the PPI by gastric acid so as to achieve its bioavailability after oral administration. In the human

fasting stomach, one would expect to encounter about 5 mEq to about 20 mEq of acid depending on age or disease. Harrison's Principles of Internal Medicine, Ch. 238, pp. 1229-48 (12th Ed. 1991). Thus, depending on age and disease, about 5 mEq to about 20 mEq of the buffering agent is needed in a non-enteric-coated dosage form to neutralize such gastric acid before substantial degradation of the PPI occurs.

As shown in the table below, the Lovgren '505 Patent fails to teach any amount of buffer even close to 5 mEq.

Amounts of Buffers of Inner Cores of Lovgren '505 Patent (Col. 6, Table 1)

Example No.	mg Buffer	Mol. Wt.	Valence	Equiv.Wt.*	Total mEq +
1	none				0
2	15 mg disodium hydrogen phosphate (disodium phosphate)	142	2	71	0.21
3	15 mg magnesium oxide	40	2	20	0.75
4	15 mg magnesium hydroxide	58	2	29	0.52
5	15 mg magnesium hydroxide and 0.2 mg disodium hydrogen phosphate	58 142	2 2	29 71	0.52 + 0.002 = 0.522
6	15 mg magnesium hydroxide	58	2	29	0.52
7	15 mg synthetic hydrotalcite	602	18	35	0.43

* Equivalent weight is calculated as the molecular weight of the buffer divided by its valence.
+ Milliequivalents (mEq) are calculated by dividing the mg of buffer by its equivalent weight.

Consequently, the Lovgren '505 Patent does not anticipate Applicant's claims.

Likewise, the disclosures of Ooishi et al. Japanese Patent Application Nos. 05255088 and 05194225 do not anticipate the claims. Again, the emphasis of these references is on using buffering agents in an intermediate core part to prevent acid degradation of the PPI by the enteric coating. Specifically, Ooishi '088 teaches:

> An **enteric** preparation produced by coating a **core part** containing benzimidazole compound that has antiulcer action and is unstable in acid with **1-2 layers of undercoating**, and then applying an **enteric coating** agent thereupon, where the enteric preparation is characterized in that **aluminum hydroxide-sodium bicarbonate coprecipitate** or the aforementioned compound and **buffering agent** is blended **in the core part and/or undercoating layers**.

Abstract, p. 1 (emphasis added).

For the core part, Ooishi '088 teaches a stabilizer of aluminum hydroxide sodium bicarbonate coprecipitate in an amount of 0.1 to 20 parts to 1 part benzimidazole compound, and buffering agents in an amount of 0.01 to 2 parts to 1 part benzimidazole compound. Such buffering agents are defined as "sodium tartrate, sodium acetate, sodium bicarbonate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogen phosphate, dipotassium hydrogen phosphate, trisodium phosphate or tripotassium phosphate.". Ooishi '088, at [0010]. However, there is no teaching that such core parts are dosage forms suitable for oral administration without an enteric coating, nor that they react with gastric acid. Therefore, Applicant's claims are not anticipated by this reference.

Ooishi et al. Japanese Patent Application No. 05194225, which was filed within weeks after the '088 application, similarly focuses on preparing enteric coated dosage forms and intermediate core parts therefor. Specifically, the reference teaches a "preparation containing

stabilized antiulcer agent, formed by blending amino acid, amino acid acid salt or amino acid alkali salt used as stabilizer, along with buffering agent, with a benzimidazole compound that has antiulcer action and is not stable in acids." Ooishi '225, at claim 1. Ooishi '225 states that this preparation can be a "tablet, granule or capsule" Ooishi '225, at claim 5; [0004]. However, when read in context of the entire specification, such tablets, granules and capsules refer to intermediate forms that are then enteric coated for the finished dosage forms. This is emphasized by Ooishi '225's description of the prior art and problems to be solved by the invention:

> With preparations such as tablets, fine powders, granules, capsules and dispersions, the compounds are influenced by other components of the preparation formula and become unstable, leading to a decrease in content and discoloration over time. Among these preparations, **when the compounds are coated to produce granules, they have poor compounding properties with respect to enteric bases** (cellulose acetate phthalate, hydroxypropylmethylcellulose phthalate, hydroxymethylcellulose acetate succinate, polyvinyl acetate phthalate, and methacrylic acid acrylic acid copolymer), and suffer content decrease and discoloration. **When an oral preparation is to be manufactured** in this manner using benzimidazole compound, in addition to problems arising from the **need for compounding with other components and the use of enteric base coatings**, there are also difficulties with formulation due to the detrimental influences on stability as described above. Consequently, it is **necessary** to appropriately stabilize these compounds when they are to be formulated in oral dosage forms.

Ooishi '225, at [0001] (emphasis added).

Section [0004] on page 5 describes how the intermediate core compositions are obtained by uniformly blending the benzimidazole compound, the amino acid, amino acid acid salt or amino acid alkali salt stabilizer, the buffering agent, additives, and water. Amounts of these substances are in the ranges of 0.01-10 parts by weight of amino acid and 0.01-10 parts by weight of buffer with respect to 1 part by weight of benzimidazole compound. The reference states further that the "resulting mixture is then finely granulated with a wet granulator, and the

material is then subjected to tabletization to produce uncoated tablets for tablet production. Alternatively, the material can be granulated using an extrusion granulator, and then formed into core granules for producing granules." Ooishi '225, at [0004] (emphasis added). The application then states that "[t]he uncoated **or** core granules **obtained in this manner** can be formed into an enteric preparation by coating the core granules with enteric coating," and that:

> The **enteric tablet or granule** that is of a dosage form that is **appropriate for oral administration** can be obtained as described above, and in addition, the granules can be packaged into capsules to produce a capsule. The **preparation obtained in this manner** experiences little change in external appearance even over long-term storage, and exhibits excellent stability with almost no decrease in content. As a result, the preparations can be used in the treatment of digestive ulcers in mammals including humans.

Ooishi '225 at [0005].

There is thus no teaching in Ooishi '225 that the intermediate tablets and granules are suitable for oral administration. Indeed, it is only the enteric "preparation obtained in this manner" from the passage above at [0005] that is appropriate for oral administration and can be used to treat digestive ulcers. Therefore, it does not anticipate Applicant's claims.

Additionally, the Lovgren and Ooishi references contain no disclosure regarding the use of flavoring or anti-foaming agents in any of the claimed dosage forms. Moreover, because there is no teaching as to the oral administration of the intermediate cores, Applicant's method claims are likewise not anticipated. Similarly, Applicant's claims to two-part dosage forms (with or without enteric-coated PPI) are not anticipated by these references because there is no teaching to use buffering agents to surround the PPI in a non-enteric coated dosage form, or to use non-enteric-coated buffering agents in combination with enteric-coated PPI.

Rejections Under 35 U.S.C. § 103

The Examiner rejected now cancelled claims 1, 4-6 as being obvious over Pilbrandt et al., Andersson et al., Landahl et al., and McCullough CA 123:237886 (flavoring, simethicone). Claims 7-14 were rejected as being obvious over Lovgren '505, Ooishi '088 and Gergely CA 123:208914 (flavoring). Applicant's new claims, however, are not obvious in view of the cited art.

Lovgren '505, Ooishi '088 and Ooishi '225 do not render obvious Applicant's new claims to solid dosage forms and compositions, or the methods for using the same in the treatment of acid-related gastrointestinal conditions. As detailed above, these references teach away from Applicant's claimed invention by emphasizing that suitable dosage forms must employ buffering agents **and** enteric coatings. There is thus a teaching away from the interaction in the stomach of a PPI and the low pH gastric secretions. Such teaching away rebuts obviousness. See In re Sponnoble, 405 F.2d 578, 587 (CCPA 1969); In re Caldwell, 319 F.2d 254, 256 (CCPA 1963).

Until now, those skilled in the art thought that the administration of an acid labile PPI without an enteric coating to be unworkable. Applicant recognized the problems associated with the delayed release dosage forms (e.g., lack of liquid forms, difficulty in swallowing by children, elderly and critically ill, slow onset of action, difficulty of manufacture, etc.) and solved them by the present invention. Consequently, Applicant's claims to dosage forms, compositions and methods employing non-enteric-coated PPI are not obvious.

Because of such a lack of expectation of success for dosage forms released in the stomach, the use of flavoring agents and anti-foaming agents such as simethicone are also non-

obvious. According to the Federal Circuit in In re Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992, "[t]here must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination." Here, as shown above, the prior art tells the skilled artisan that PPIs must be enteric-coated and, therefore, there was no reason or suggestion to use flavoring agents or anti-foaming agents because such agents would serve no purpose with the enteric-coated forms of the prior art. Thus, Gergely and McCullough fail to render Applicant's claims obvious.

Applicant also submits that its claims to liquid pharmaceutical compositions are not obvious over Pilbrant, et al., Andersson, et al., Landahl, et al., Gergely and McCullough. Applicant's product by process claims are directed to combining the novel dosage forms and compositions with an aqueous medium. Pilbrant teaches a suspension of 60 mg omeprazole (micronized) in 50ml of water containing 8 mmoles of sodium bicarbonate. Andersson teaches omeprazole solutions created by dissolving the drug in a sodium bicarbonate/PEG400 solution. Landahl also teaches the dissolution of omeprazole in a solution of sodium bicarbonate and PEG 400. Consequently, none of these references teach or suggest combining a dry dosage form of PPI and a buffer with an aqueous diluent. Indeed, with the prior art teaching that non-enteric-coated forms are unstable to humidity (See Lovgren '505 patent, Col. 1-2), and that they must be enteric-coated, there was no expectation that such forms would be stable, let alone that they could be used to create liquid forms. Therefore, Applicant's claims are patentable over the cited art.

Support in Specification for New Claims

Per the Examiner's request, the support for the new generic claims are detailed in the table below.

Claim No.	Support Exists at Least on These Pages
23-94	24, 26-46
95-140	24-46
141-180	24-46
181-202	24; 34-36; 48
203-237	34-36
238-265	24; 27; 66
266-291	24; 27; 66

Claims 292-625 to omeprazole and lansoprazole correspond to the above generic claims, and support can be found for the same on these pages.

This application is now in condition for allowance. The Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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